U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE

HEARING CHARTER

Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?

Thursday, September 21, 2006
10:00 a.m. - Noon
2318 Rayburn House Office Building

1. Purpose

On Thursday, September 21, 2006, the Committee on Science of the House of Representatives will hold a hearing to examine whether the federal government is adequately funding, prioritizing, and coordinating research on the environmental and safety impacts of nanotechnology.

2. Witnesses

Dr. Norris E. Alderson is the Chair of the interagency Nanotechnology Environmental and Health Implications Working Group and the Associate Commissioner for Science at the Food and Drug Administration (FDA).

Dr. Arden L. Bement, Jr. is the Director of the National Science Foundation (NSF).

Dr. William Farland is the Deputy Assistant Administrator for Science in the Office of Research and Development at the Environmental Protection Agency (EPA).

Dr. Altaf H. (Tof) Carim is a Program Manager in the Nanoscale Science and Electron Scattering Center at the Office of Basic Energy Sciences in the Department of Energy (DOE).

Dr. Andrew Maynard is the Chief Science Advisor for the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars.

Mr. Matthew M. Nordan is the President and Director of Research at Lux Research Inc., a nanotechnology research and advisory firm.

3. Overarching Questions

- How much is the federal government spending on research on environmental and safety impacts of nanotechnology? How are funding levels determined? Are current federal research efforts adequate to address concerns about environmental and safety ramifications of nanotechnology?

- What are the priorities for federally-supported research on the environmental and safety impacts of nanotechnology? How are these priorities determined, and are the current priorities appropriate?

- What impacts are environmental and safety concerns having on the development of nanotechnology-related products and their entry into the marketplace? What impact might these concerns have in the future?

- Are additional steps needed to improve management and coordination of federal research in this area?

4. Brief Overview

- Nanotechnology, the science of materials and devices of the scale of atoms and molecules, has entered the consumer marketplace. Today, there are over 300[1] products on the market claiming to contain nanomaterials (materials engineered using nanotechnology or containing nano-sized particles), generating an estimated $32 billion in revenue.[2] By 2014, according to Lux Research,[3] a private research firm that focuses on nanotechnology, there could be $2.6 trillion worth of products in the global marketplace which have incorporated nanotechnology.

- There is significant concern in industry that the projected economic growth of nanotechnology could be undermined by either real environmental and safety risks of nanotechnology or the public's perception that such risks exist. Recently, some reports have indicated that these concerns are causing some companies to shy away from nanotechnology-related products and downplay nanotechnology when they talk about or advertise their products. There is an unusual level of agreement among researchers, and business and environmental organizations that the basic scientific information needed to assess and protect against potential risks does not yet exist.

- The President's fiscal year 2007 (FY07) budget requests $1.3 billion for the National Nanotechnology Initiative (NNI), the interagency nanotechnology research and development (R&D) program. Of this amount, the budget proposes $44.1 million (3.5 percent of the overall program) for research on environmental and safety implications of nanotechnology. This is $6.6 million above the FY06 funding level. Nearly 60 percent of this funding would go to NSF.

- In October 2003, the White House National Science and Technology Council organized an interagency Nanotechnology Environmental and Health Implications (NEHI) Working Group, composed of agencies with research and regulatory responsibilities for nanotechnology, to coordinate environmental and safety research. The NEHI Working Group

[1] Wilson Center, Project on Emerging Nanotechnologies, "Nanotechnology: A Research Strategy for Addressing Risk" July, 2006. p. 4.
[2] Lux Research, "Taking Action on Nanotech Environmental, Health, and Safety Risks," Advisory, May 2006 (NTS-R-06-003) (hereafter cited as "Taking Action").
[3] Lux Research, "Sizing Nanotechnology's Value Chain," October 2004.

is charged with "facilitate[ing] the identification, prioritization, and implementation of research…required for the responsible" development and use of nanotechnology.[4] The Food and Drug Administration serves as the current Chair of the NEHI Working Group.

- One of the NEHI Working Group's initial tasks was developing a report describing research needs for assessing and managing the potential environmental and safety risks of nanotechnology. In March 2006, the Administration informed the Science Committee that this report would be completed that spring, but the document has not yet been released.

- In July 2006, the Wilson Center's Project on Emerging Nanotechnologies released a report proposing a research strategy for "systematically exploring the potential risks of nanotechnology." The report highlights critical federal research that urgently needs to be carried out in the next two years and recommends that a non-governmental organization, such as the National Academy of Sciences, develop and regularly review a long-term research strategy. The report also finds that current federal coordination does not yet have an effective mechanism to set research priorities, distribute tasks among the agencies, and ensure that adequate resources are provided for the most urgent research.

5. Previous Science Committee Hearing

The Science Committee held a previous hearing on this topic, *Environmental and Safety Impacts of Nanotechnology: What Research is Needed?,* on November 17, 2005. The charter for that hearing is attached (Appendix A). At that hearing, witnesses from the federal government, industry, and environmental organization agreed that relatively little is understood about the environmental and safety implications of nanotechnology. The non-governmental witnesses emphasized that, for the emerging field of nanotechnology to reach its full economic potential, the federal government must significantly increase funding for research in this area.

6. Developments Since November 2005

Fiscal Year 2007 Budget

In July 2006, the Administration released its nanotechnology supplement to the President's FY07 budget request.[5] This document includes information about the overall funding levels for research on environment and safety impacts of nanotechnology at each of the federal agencies participating in the NNI (see Table 1). The budget supplement also provides brief descriptions of some of the activities underway in this area, and highlights FY07 initiatives such as the expansion of a joint grant program among EPA, NSF, the National Institute for Occupational Safety and Health (NIOSH) and the National Institute of Environmental Health Sciences (NIEHS), but it does not provide funding levels for specific research activities. (NIOSH is part of the Department of Health and Human Services (DHHS), and NIEHS is part of the National Institutes of Health (NIH), also part of DHHS.) To help the agencies determine how to estimate

[4] Terms of Reference, Nanotechnology Environmental and Health Implications Working Group Nanoscale Science, Engineering, and Technology Subcommittee Committee on Technology; March, 2005.
[5] The National Nanotechnology Initiative: "Research and Development Leading to a Revolution in Technology and Industry, Supplement to the President's FY 2007 Budget."
http://www.ostp.gov/nstc/html/NNI%2007%20Budget%20Supplement%20July%202007.pdf

the funding levels reported in Table 1, the National Nanotechnology Coordinating Office provides a definition of "Environment Health, and Safety Implications Research and Development (R&D)," but the agencies' application of the definition to their programs can vary.

Table 1: NNI Proposed FY07 Investments in Research on Environmental and Safety Implications of Nanotechnology ($ in millions)

Agency	Total Spending on Nanotechnology R&D (FY07 Proposed)	Environment Health, and Safety Implications R&D (FY07 Proposed)	Percent of Total Environment, Health and Safety Implications R&D
NSF	373.0	25.7	58.3%
DOD	345.0	1.0	2.3%
DOE	258.0	0.0	0.0%
DHHS (NIH)	170.0	4.6	10.4%
DOC (NIST)	86.0	1.8	4.1%
NASA	25.0	0.0	0.0%
EPA	9.0	8.0	18.1%
USDA (CSREES)	3.0	0.1	0.2%
DHHS (NIOSH)	3.0	3.0	6.8%
USDA (FS)	2.0	0.0	0.0%
DHS	2.0	0.0	0.0%
DOJ	1.0	0.0	0.0%
DOT (FHWA)	0.1	0.0	0.0%
TOTAL	**1,278.0**	**44.1**	**100.0%**

Acronyms
CSREES = Cooperative State, Research, and Education Extension Service (within USDA)
DHS = Department of Homeland Security
DOC = Department of Commerce
DOD = Department of Defense
DOJ = Department of Justice
DOT = Department of Transportation
FHWA = Federal Highway and Works Administration (within DOT)
FS = Forest Service (within USDA)
NASA = National Aeronautics and Space Administration
USDA = U.S. Department of Agriculture

Report on Federal Priorities for Research on Environmental and Safety Implications of Nanotechnology Is Not Completed

At the Science Committee's November 17, 2005 hearing on nanotechnology, Dr. Clayton Teague, Director of the National Nanotechnology Coordination Office, testified that the NEHI Working Group was "preparing a document that identifies and prioritizes information and research needs in this area. The document will serve as a guide to the NNI agencies as they develop budgets and programs and will inform individual investigators as they consider their research directions."[6] In his responses to questions for the record, Dr. Teague said the report was

[6] Clayton Teague Testimony, November 17, 2005, House Science Committee, p. 3.

expected to be completed by "Spring 2006" and "is intended to be sufficiently detailed to guide investigators and managers in making project-level decisions, yet broad enough to provide a framework for the next five to ten years." The report has not yet been completed and no drafts have been released for public comment.

For the final document to provide useful guidance to agencies, Congress, industry academic researchers, environmental groups, and the public, it will need to define the scale and scope of the needed research, set priorities for research areas, provide information that can affect agency-directed spending decisions, and be specific enough to serve as overall research strategy for federal and non-federal research efforts. In the absence of such a document, each agency can only set its priorities and funding levels based on its individual mission rather than in the context of other agencies' needs or activities.

Recent Reports

In the past year, five new reports have been published that characterize how the private sector is coping with environmental and safety implications of nanotechnology and how the federal government is funding and should be prioritizing its research in this area. Three of the most significant new reports are summarized below.[7] In addition, this week the Wilson Center released the results of a national poll indicating that the majority of the public still has heard little to nothing about nanotechnology. The poll also finds that the public looks to the federal government and independent parties to monitor nanotechnology research and products. These findings bolster earlier calls by Congress, businesses, and environmental groups for the federal government to prioritize and provide more support for critical research on understanding the risks associated with nanotechnology so as to inform the public and enable the responsible development of nanotechnology.

<u>Lux Research Report</u>

In May 2006, Lux Research, a business research and advisory firm specializing in nanotechnology, released a report[8] updating its May 2005 assessment[9] of the environment and safety landscape for businesses involved with nanotechnology. According to Lux, the debate about the environmental and safety implications of nanotechnology has "intensified," while the continuing lack of data, tools, and protocols for answering key safety questions is creating significant challenges for companies interested in developing nanotechnology-related products and their potential investors.

[7] In addition to the three reports described in detail in this charter, Guy Carpenter & Company, Inc. a leading risk and reinsurance specialist and a part of the Marsh & McLennan Companies, Inc. published a report in August 2006 titled, "Nanotechnolgy: The Plastics of the 21st Century." The report provides businesses and risk managers with an overview of the field and some of the environmental issues that can be expected to arise relating to insurance and government regulation. In another important report issued just before the Science Committee's Nov 2005 hearing, Innovest, an investment research firm that rates companies on their environmental management and performance, issued a report titled, " Nanotechnology" (October 2005), in which it introduced an investment index for investors. The report discusses the market viability of nano-products and materials in light of environmental and safety issues that could play a role in commercialization and in company performance. It also provides an overview of company best practices. The report distills a list of 300 public and private companies found in NanoInvestornews.com down to an index of 15 companies, and a watch list of an additional eight companies. Innovest is tracking the indexed companies and updates its findings for clients.

[8] Lux Research, "Taking Action," 2006.

[9] Lux Research, "A Prudent Approach to Nanotech Environmental, Health and Safety Risks." May 2005.

Some large companies are shying away from nanotechnology-related products because they fear potential liabilities or the costs of extensive toxicity testing. Smaller, nanotechnology-focused companies, on the other hand, cannot leave the field, but are unable to afford to provide the data on the safety of their products increasingly requested by their customers. There are some signs that companies unsure of how to deal with potential risks may be trying to sidestep the issue by simply not using the term "nanotechnology" in their product descriptions.

The Lux report notes that many environmental groups have advocated for increased funding for research on the environmental and safety implications of nanotechnology and several have called for temporary or permanent moratoria on nanotechnology products. The report also suggests that regulation by agencies such as EPA, FDA, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission, is in the offing, but notes that the timing and substance of regulatory action remain uncertain. Many companies have been pressing these agencies to provide information about their plans in this area and to take actions that will reduce the uncertainty surrounding regulation of nanotechnology.

Due to the uncertainty of the current research and regulatory environments, the Lux report recommends that companies develop their own plans to address potential real and perceived risks of nanomaterials and products. The Lux report does not include any recommendations for the research or regulatory agencies of the federal government.

Wilson Center Inventory of Research on the Environmental and Safety Impacts of Nanotechnology

As was discussed at the Science Committee's last hearing on this topic, in 2005 the Wilson Center began assembling an inventory of ongoing research into the environmental and safety impacts of nanotechnology; the analysis of this inventory was released just after the hearing in November 2005.[10] The inventory catalogs research funded by governments around the world as well as some research funded by industry and foundations. The primary purpose of the inventory is to facilitate strategic, coordinated and integrated research among the public and private sectors on research in this area. While the inventory is not complete, it includes all the available public information on federally-sponsored research.

The Wilson Center's initial analysis[11] of the inventory highlights two main points. The first is that significant gaps exist in the current portfolio of federally supported research projects. For example, the Wilson Center found few projects focused on controlling or preventing exposure to engineered nanomaterials and their release into the environment, as well as little research into the diseases and environmental impacts that may result from exposure. While there were many research projects studying the hazards of exposure to nanoparticles, most research focused on the lungs, with no projects focusing on the gastrointestinal tract. The Wilson Center's research needs report, described in the next section, suggests that these gaps in the research portfolio may

[10] The Wilson Center inventory continues to be updated; the most current version is available online at http://www.nanotechproject.org/18. Information from the inventory was included in the November 17, 2005 hearing record.
[11] This analysis was performed on the inventory as of November 23, 2005.

reflect the absence of an overall federal strategy for conducting research on the environmental and safety impacts of nanotechnology.

The second main finding of the analysis is the inconsistency between the Wilson Center inventory and the federal budget supplement. The Wilson Center found $31 million worth of research projects funded by the U.S. government in 2005 that had some relevance to the potential environmental and safety risks of nanotechnology. However, only $11 million of the $31 million was going to projects that specifically focused on the environmental or safety implications of nanotechnology. In contrast, the FY07 NNI budget supplement states that, in FY05, the federal agencies in NNI spent $35 million on research for which the primary purpose was understanding and addressing potential environmental and safety risks of nanotechnology. The Wilson Center inventory includes the available public information on federally sponsored research, and since the NNI has not developed its own detailed inventory of projects in this area, it is not currently possible to determine why these accountings differ.

Table 2. Comparison of NNI-reported funding for research on environmental and safety implications of nanotechnology and data on funding levels in that area gathered by the Wilson Center in 2005. (Dollars are in millions.)

Agency	NNI-Reported: Environment Health, and Safety Implications Research (FY05 Actual)	Wilson Center Reported: Risk-Related Research (all relevant research)	Wilson Center Reported: Risk-Related Research (highly relevant research)
NSF	20.9	19.0	2.5
DOD	1.0	1.1	1.1
DOE	0.5	0.3	-
DHHS (NIH)	2.7	3.0	3.0
DOC (NIST)	0.0	1.0	-
EPA	6.7	2.6	2.3
USDA (CSREES)	0.1	-	-
DHHS (NIOSH)	3.0	3.1	1.9
USDA/FS	-	0.5	-
TOTAL	**34.8**	**30.6**	**10.8**

Wilson Center, "Nanotechnology: A Research Strategy for Addressing Risk"

In July 2006, Dr. Andrew Maynard, the Wilson Center's Chief Scientist, and a former NIOSH scientist, proposed a research strategy for "systematically exploring the potential risks of nanotechnology."[12] Based on the significant knowledge gaps identified in a variety of research needs reports from federal agencies, private groups, and international bodies; the Wilson Center's inventory of research in this area; his own experience in interagency activities while at NIOSH; and a risk-based framework that he developed, the report outlines the highest priority areas of research in which investment is needed between 2007 and 2009 to ensure the safety of technologies in use or close to commercialization and lay the groundwork for future research

[12] Wilson Center, Project on Emerging Nanotechnologies, "Nanotechnology: A Research Strategy for Addressing Risk" July, 2006.

needs. The highest short-term priorities include identifying and measuring exposure and environmental releases, assessing toxicity, controlling releases, and developing best practices for worker safety, while longer-term needs include investment in areas such as predictive toxicology, the ability to predict the toxicological effects of nanomaterials.

The report also makes recommendations for changes in federal nanotechnology programs to ensure that the appropriate investments are made and the programs are carried out effectively. First, the report calls for the federal government to shift funding for research on environmental and safety impacts of nanotechnology to those federal agencies with clear mandates and expertise in risk-related research, including EPA, NIOSH, NIEHS, and NIST, and the analysis in the report suggests that these agencies will require a minimum of $100 million over the next two years to carry out the needed research. The report also expresses concern that the current interagency process is insufficient and that gaps in the research portfolio are resulting from a bottom-up approach in which each agency develops its own research priorities. The report therefore recommends the establishment of a new interagency oversight group with the "authority to set and implement a strategic research agenda" and to assure adequate resources for those agencies carrying out the highest priority research.

The report also recommends that the federal government work closely with outside groups in executing research in this area. It says that mechanisms are needed to facilitate government-industry research partnerships and to enable international collaboration and information sharing. It cites the Health Effects Institute, an organization that has effectively addressed controversial air pollution research through joint government and private sector funding, as an excellent model for what is needed.[13] It also calls for international cooperation to share research costs and exchange information.

The report also calls for a long-term research strategy to be developed and reviewed regularly by an organization such as the National Academies. This recommendation is consistent with the recommendation made by Dr. Richard Denison, of the environmental organization Environmental Defense, in his testimony before the committee at the November 17, 2005 hearing.

7. Witness Questions

Questions for Dr. Norris Alderson, Food and Drug Administration

In your testimony, please briefly describe the responsibilities and activities of the National Nanotechnology Environmental and Health Implications (NEHI) Working Group and address the following questions:

- What are the overall priorities for federally-supported research on the environmental and safety impacts of nanotechnology and how are these priorities determined? To what extent is the NEHI Working Group involved in setting or recommending funding levels for research in

[13] The Health Effects Institute (HEI) is as an independent, non-profit research organization, chartered in 1980, to provide high-quality, impartial, and relevant science on the health effects of air pollution. Typically, HEI receives half of its core funds from the EPA and half from the worldwide motor vehicle industry. http://www.healtheffects.org

these areas? How are research roles allocated among the different agencies? How are ongoing research activities coordinated?

- When will the federal report that describes research needs for assessing and managing the potential risks of nanotechnology be completed and released? How is the NEHI Working Group incorporating information about risk and about the research needs of federal regulatory activities into the research needs document? How is input from groups outside of government, including industry, incorporated?
- What topics will the report cover and what issues will remain to be addressed in the future? What will be the responsibilities and activities of the NEHI Working Group once the report is complete?

Questions for Dr. Arden Bement, National Science Foundation

In your testimony, please briefly describe NSF's current and proposed fiscal year 2007 programs and funding for research on possible environmental and safety risks associated with nanotechnology, and address the following questions:

- What are your agency's research priorities for studies of environmental and safety impacts of nanotechnology? How were these priorities determined, and what would cause them to change? To what extent is your research agenda specifically designed to inform potential regulation? How have you decided what portion of your nanotechnology funding to allocate to research in this area?
- In what specific ways has your agency's research agenda been shaped by interagency coordination? Are there areas of research you are conducting because they have not been taken up by other agencies or areas that you are forgoing because other agencies are taking on that research? Is there research being done because of the specific needs of regulatory agencies?

Questions for Dr. William Farland, Environmental Protection Agency

In your testimony, please briefly describe EPA's current and proposed fiscal year 2007 programs and funding for research on possible environmental and safety risks associated with nanotechnology and address the following questions:

- What are your agency's research priorities for studies of environmental and safety impacts of nanotechnology? How were these priorities determined, and what would cause them to change? To what extent is your research agenda specifically designed to inform potential regulation? How have you decided what portion of your research funding to allocate to nanotechnology-related projects?
- In what specific ways has your agency's research agenda been shaped by interagency coordination? Are there areas of research you are conducting because they have not been taken up by other agencies or areas that you are forgoing because other agencies are taking on that research? Is there research being done because of the specific needs of regulatory agencies?

Questions for Dr. Altaf (Tof) Carim, Department of Energy

In your testimony, please briefly describe the Department of Energy's current and proposed Fiscal Year 2007 (FY07) programs and funding for research on possible environmental and safety risks associated with nanotechnology and address the following questions:

- What are your agency's research priorities for studies of environmental and safety impacts of nanotechnology? How were these priorities determined, and what would cause them to change? To what extent is your research agenda specifically designed to inform potential regulation? How have you decided what portion of your nanotechnology funding to allocate to research in this area?
- In what specific ways has your agency's research agenda been shaped by interagency coordination? Are there areas of research you are conducting because they have not been taken up by other agencies or areas that you are forgoing because other agencies are taking on that research? Is there research being done because of the specific needs of regulatory agencies?

Questions for Dr. Andrew Maynard, Project on Emerging Nanotechnologies, Woodrow Wilson Center

In your testimony, please briefly describe the results of the Wilson Center's inventory of federal research on the environmental and safety impacts of nanotechnology and the report, "Nanotechnology: A Research Strategy for Addressing Risk?", and address the following questions:

- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? Are there gaps in the portfolio of federal research currently underway; if so, in what areas?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? How should the responsibility for funding and conducting this research be divided among the federal agencies, industry, and universities?
- What elements should the forthcoming report on research needs produced by the National Nanotechnology Environmental and Health Implications Working Group contain to adequately guide federal research investment in this area? What additional steps are needed to improve management and coordination of federal research on the environmental and safety impacts of nanotechnology?

Questions for Mr. Matthew Nordan, Lux Research

Please address the following questions in your testimony:

- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?

- What should be the priority areas of research on environmental and safety impacts of nanotechnology? How should the responsibility for funding and conducting this research be divided among the federal agencies, industry, and universities?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? Are there gaps in the portfolio of federal research currently underway; if so, in what areas?
- What additional steps are needed to improve management and coordination of the federal government's research enterprise?

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE

HEARING CHARTER

Environmental and Safety Impacts of Nanotechnology: What Research is Needed?

Thursday, November 17, 2005
10:00 a.m. - Noon
2318 Rayburn House Office Building

1. Purpose

On Thursday, November 17, 2005, the Committee on Science of the House of Representatives will hold a hearing to examine current concerns about environmental and safety impacts of nanotechnology and the status and adequacy of related research programs and plans. The federal government, industry and environmental groups all agree that relatively little is understood about the environmental and safety implications of nanotechnology and that greater knowledge is needed to enable a nanotechnology industry to develop and to protect the public. The hearing is designed to assess the current state of knowledge of, and the current research plans on the environmental and safety implications of nanotechnology.

2. Witnesses

Dr. Clayton Teague is the Director of the National Nanotechnology Coordination Office, the office that coordinates Federal nanotechnology programs. The office is the staff arm of the Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council (NSTC). NSTC includes all federal research and development (R&D) agencies and is the primary coordination group for federal R&D policy.

Mr. Matthew M. Nordan is the Vice President of Research at Lux Research Inc., a nanotechnology research and advisory firm.

Dr. Krishna C. Doraiswamy is the Research Planning Manager at DuPont Central Research and Development, and is responsible for coordinating DuPont's nanotechnology efforts across the company's business units.

Mr. David Rejeski is the Director of the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars.

Dr. Richard Denison is a Senior Scientist at Environmental Defense.

3. Overarching Questions

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?

- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?

- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?

- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

4. Brief Overview

- Nanotechnology is expected to become a major engine of economic growth in the coming years. According to Lux Research,[14] a private research firm that focuses on nanotechnology, in 2014 there could be $2.6 trillion worth of products in the global marketplace which have incorporated nanotechnology —15 percent of manufacturing output. Lux also predicts that in 2014, 10 million manufacturing jobs worldwide—11 percent of total manufacturing jobs—will involve manufacturing these nanotechnology-enabled products.

- There is a growing concern in industry that the projected economic growth of nanotechnology could be undermined by real environmental and safety risks of nanotechnology or the public's perception that such risks exist.

- The small size, large surface area and unique behavioral characteristics of nanoparticles present distinctive challenges for those trying to assess whether these particles pose potential environmental risks. For example, nanoscale materials such as buckyballs, nano-sized clusters of carbon atoms, behave very differently than their chemically-equivalent cousin, pencil lead. There is an unusual level of agreement among researchers, and business and environmental organizations that basic scientific information needed to assess and protect against potential risks does not yet exist.

- In December 2003, the President signed the *21st Century National Nanotechnology Research and Development Act* (P.L. 108-153), which originated in the Science Committee. This Act provided a statutory framework for the interagency National Nanotechnology Initiative (NNI). Among other activities, the Act called for the NNI to ensure that research on environmental concerns is integrated with broader federal nanotechnology research and development (R&D) activities.

[14] Lux Research, "Sizing Nanotechnology's Value Chain," October 2004.

- Federal funding for the NNI has grown from $464 million in fiscal year 2001 (FY01) to a requested $1.1 billion in FY06. Of the requested FY06 level, the President's budget proposes that $38.5 million (4 percent of the overall program) be directed to research on environmental and safety implications of nanotechnology.

5. Background

The National Academy of Sciences describes nanotechnology as the "ability to manipulate and characterize matter at the level of single atoms and small groups of atoms." An Academy report describes how "small numbers of atoms or molecules ... often have properties (such as strength, electrical resistivity, electrical conductivity, and optical absorption) that are significantly different from the properties of the same matter at either the single-molecule scale or the bulk scale." [15]

Nanotechnology is an enabling technology that will lead to "materials and systems with dramatic new properties relevant to virtually every sector of the economy, such as medicine, telecommunications, and computers, and to areas of national interest such as homeland security."[16] As an enabling technology, it is expected to be incorporated into existing products, resulting in new and improved versions of these products. Some nanotechnology-enabled products are already on the market, including stain-resistant, wrinkle-free pants, ultraviolet-light blocking sunscreens, and scratch-free coatings for eyeglasses and windows. In the longer run, nanotechnology may produce revolutionary advances in a variety of industries, such as faster computers, lighter and stronger materials for aircraft, more effective and less invasive ways to find and treat cancer, and more efficient ways to store and transport electricity.

The projected economic growth of nanotechnology is staggering. In October 2004, Lux Research, a private research firm, released its most recent evaluation of the potential impact of nanotechnology. The analysis found that, in 2004, $13 billion worth of products in the global marketplace incorporated nanotechnology. The report projected that, by 2014, this figure will rise to $2.6 trillion—15 percent of manufacturing output in that year. The report also predicts that in 2014, ten million manufacturing jobs worldwide—11 percent of total manufacturing jobs—will involve manufacturing these nanotechnology-enabled products.[17]

[15] *Small Wonders, Endless Frontiers: A Review of the National Nanotechnology Initiative*, National Research Council/National Academy of Sciences, 2002.
[16] Id.
[17] Lux Research, "Sizing Nanotechnology's Value Chain," October 2004.

6. How Might Environmental and Safety Risks Affect the Commercialization of Nanotechnology?

Lux Research Report on Environmental and Safety Risks of Nanotechnology

In May, 2005, Lux Research published a comprehensive analysis of how environmental and safety risks could affect the commercialization of nanotechnology.[18] While a limited number of studies have been done on specific environmental impacts, the report concludes that the few that have been done raise sufficient cause for concern. This leads to what the report calls a fundamental paradox facing companies developing nanotechnology: "They must plan for risks without knowing precisely what they are." The report then identifies two classes of risk that are expected to effect commercialization: "*real* risks that nanoparticles may be hazardous and *perceptual* risks that they pose a threat regardless of whether or not it is real." The report calculates that at least 25 percent of the $8 trillion in total projected revenue from products incorporating nanotechnology between 2004 and 2014 could be affected by real risks and 38 percent could be affected by perceived risk."

The report describes that varying levels of risk are suspected for different types of nanomaterials and products and for different phases of a product's life cycle. For example, some nanoclay particles raise little initial concern because they would be locked up in composites to be used in automotive bodies. On the other hand, cadmium-selenide quantum dots that could be injected into the body for medical imaging tests are highly worrisome due to the toxicity of cadmium-selenide and the fact that they would be used within the human body.

Another factor that contributes to the potential risk of different nanotechnology-related products is the expected exposure of people and the environment over the product's life cycle. The manufacturing phase is the first area of concern because workers potentially face repeated exposure to large amounts of nanomaterials.[19] During product use, the actual risk will vary depending in part on whether the nanoparticles have been fixed permanently in a product, like within a memory chip in a computer, or are more bioavailable, like in a sunscreen where exposure may be more direct or may continue over a long period of time. Finally, the greatest uncertainties exist about the risks associated with the end of a product's life because it is difficult to predict what method of disposal, such as incineration or land disposal, will be used for a given material, and there has been little research on, for example, what will happen to nanomaterials within products stored in a landfill over 100 years.

The Lux Research report finds that nanotechnology also faces significant perceived risks. These risks are driven by people's general concerns about new technologies that they may be exposed to without being aware of it. However, public perceptions of nanotechnology are still up in the air and may be influenced by the press and non-governmental organizations. The report argues that, with a concerted effort to emphasize the benefits of nanotechnology, communicate honest

[18] Lux Research, "A Prudent Approach to Nanotech Environmental, Health and Safety Risks." May 2005

[19] Lux Research's findings on worker exposure are consistent with the concerns expressed in the recent report on the NNI by the President's Council of Advisors on Science and Technology. The report, *National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel*, is available online at http://www.nano.gov/FINAL_PCAST_NANO_REPORT.pdf.

assessments of toxicological effects, and engage all interested stakeholders from the outset, the public could be made comfortable with this new technology.

Woodrow Wilson International Center Study on Public Perceptions

A more in-depth survey of public perception of nanotechnology was recently completed by Woodrow Wilson Center's Project on Emerging Technologies.[20] The study found that the public currently has little knowledge about nanotechnology or about how risks from nanotechnology will be managed. This lack of information can lead to mistrust and suspicion. However, the study shows that when people learned more about nanotechnology and its promised benefits, approximately 80 percent were supportive or neutral about it. Once informed, people also expressed a strong preference for having more information made available to the public, having more testing done before products were introduced, and having an effective regulatory system. They do not trust voluntary approaches and tend to be suspicious of industry. The lesson, according to the report, is that there is still time to shape public perception and to ensure that nanotechnology is developed in a way that provides the public with information it wants and establishes a reasonable regulatory framework.

7. Emerging Environmental and Safety Concerns

Initial research on the environmental impacts of nanotechnology has raised concerns. For example, early research on buckyballs (nano-sized clusters of 60 carbon atoms) suggests that they may accumulate in fish tissue. Although it may turn out that many, if not most, nanomaterials will be proven safe in and of themselves and within a wide variety of products, more research is needed before scientists can determine how they will interact with people and the environment in a variety of situations.

Nanotechnology's potential to affect many industries stem from that fact that many nanoscale materials behave differently than their macroscale counterparts. For example, nano-sized quantities of some electrical insulating materials become conductive, insoluble substances may become soluble, some metals become explosive, and materials may change color or become transparent. These novel features create tremendous opportunities for new and exciting applications, but also enable potentially troubling new ways for known materials to interact with the human body or be transported through the environment. It is difficult and would be misleading to extrapolate from current scientific knowledge on how materials behave in their macro-form to how they will behave in nano-form, and new techniques to assess toxicity, exposure, and ultimately public and environmental risks from these materials may be needed.

Widely Recognized Research and Development Needs

Businesses, non-governmental organizations, academic researchers, federal agencies, and voluntary standards organizations all have efforts underway to address concerns about the environmental and safety implications of nanotechnology. However, a number of organizations,

[20] *Informed Public Perception of Nanotechnology and Trust in Government*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars is available online at http://www.pewtrusts.com/pdf/Nanotech_0905.pdf.

including business associations and environmental groups, worry that environmental R&D is not keeping pace with the rapid commercialization and development of new nanotechnology-related products. There is widespread agreement on the following research and standards needs:

- Nanotechnology needs an accepted nomenclature. For example, "buckyballs" is the equivalent of a trade name; it does not convey critical information about the content, structure, or behavior of nanoparticles as traditional chemical nomenclature does for traditional chemicals. The lack of nomenclature creates a variety of problems. For example, it is difficult for researchers to know whether the nanomaterial they are working with is the same as that presented in other research papers. Similarly, it is difficult for a company to know whether it is buying the same nanomaterial from one company that it previously bought from another.

- Nanotechnology needs an agreed upon method for characterizing particles. Nanoparticles unique size enables unusual behavior. At these small sizes, particles can have different optical and electrical properties than larger particles of the same material. In addition, the large surface area of nanoparticles relative to their mass makes nanoparticles more reactive with their surroundings. Further complicating efforts to characterize nanomaterials is that small changes to some nanoparticles, such as altering the coatings of buckyballs, significantly modify the physical properties (and hence the potential toxicity) of the particles.

- A great deal more information is needed on the mechanisms of nanoparticle toxicity. Early studies suggest that a variety of nanoparticles damage cells through oxidative stress. (Oxidation is believed to be a common source of many diseases such as cancer.) A better understanding of the chemical reactions that nanoparticles provoke or take part in within living organisms will enable researchers to more effectively predict which nanomaterials are most likely to cause problems.

- Basic information on how nanomaterials enter and move through the human body are needed. Early studies point to wide variations in the toxicity of nanomaterials depending on the how exposure occurred – through the mouth, skin contact, inhalation, or intravenously. Particles in the range of 1-100 nanometers are small enough to pass through cell walls and through the blood-brain barrier, making them particularly mobile once they enter the body. There is also concern that some nanoparticles could lodge in the lungs and might be so small as to be overlooked by the body's defense mechanisms that would normally remove these invaders from the body.

- More research is needed on how and why some nanoparticles appear to behave one way as individual particles, but behave differently when they accumulate or agglomerate. One study of buckyballs, for example, found that while individual buckyballs are relatively insoluble, they have a tendency to aggregate, which makes them highly soluble and reactive with bacteria, raising concerns about their transport in watersheds and their impact on ecosystems.

According to a variety of experts, many of whom are familiar with the development of the largely mature databases available on the behavior and toxicity of various chemicals,

development of a parallel collection of information on nanotechnology-related materials may take as long as 10-15 years.

Call for a Governmental Program on Environmental and Safety Implications of Nanotechnology

Recently, the American Chemistry Council and the environmental organization, Environmental Defense, agreed on a Joint Statement of Principles that should guide a governmental program for addressing the potential risks of nanoscale materials.[21] They call for, among other things,

- "a significant increase in government investment in research on the health and environmental implications of nanotechnology,"
- "the timely and responsible development of regulation of nanomaterials in an open and transparent process,"
- "an international effort to standardize test protocols, hazard and exposure assessment approaches and nomenclature and terminology,"
- "appropriate protective measures while more is learned about potential human health or environmental hazards," and
- a government assessment of "the appropriateness of or need for modification of existing regulatory frameworks."

8. Federal Government Activities

The National Nanotechnology Initiative (NNI) is a multi-agency research and development (R&D) program begun in 2001 and formally authorized by Congress in 2003.[22] Currently, 11 federal agencies have ongoing programs in nanotechnology R&D, while another 11 agencies participate in the coordination and planning work associated with the NNI. The primary goals of the NNI are to foster the development of nanotechnology and coordinate federal R&D activities.[23]

Federal funding for the NNI has grown from $464 million in FY01 to a requested $1.1 billion in FY06. Of the requested FY06 level, the President's budget proposes that $38.5 million (4

[21] Environmental Defense and American Chemistry Council Nanotechnology Panel, Joint Statement of Principles, Comments on EPA's Notice of Public Meeting on Nanoscale Materials, June 23, 2005. The full statement is available online at http://www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf.

[22] In 2003, the Science Committee wrote and held hearings on the *21st Century National Nanotechnology Research and Development Act*, which was signed into law on December 3, 2003. The Act authorizes $3.7 billion over four years (FY05 to FY08) for five agencies (the National Science Foundation, the Department of Energy, the National Institute of Standards and Technology, the National Aeronautics and Space Administration, and the Environmental Protection Agency). The Act also: adds oversight mechanisms—an interagency committee, annual reports to congress, an advisory committee, and external reviews—to provide for planning, management, and coordination of the program; encourages partnerships between academia and industry; encourages expanded nanotechnology research and education and training programs; and emphasizes the importance of research into societal concerns related to nanotechnology to understand the impact of new products on health and the environment.

[23] The goals of the NNI are to maintain a world-class research and development program; to facilitate technology transfer; to develop educational resources, a skilled workforce, and the infrastructure and tools to support the advancement of nanotechnology; and to support responsible development of nanotechnology.

percent of the overall program) be directed to research on environmental, health, and safety implications of nanotechnology (see Table 1).[24]

Table 1. NNI Proposed FY2006 Investments in environmental implications ($ in millions)

Agency	Total Spending on Nanotechnology R&D	Environment, Health and Safety Implications R&D	Percent of Total Environment, Health and Safety Implications R&D
NSF	$344	$24.0	62.3
DOD	$230	$1.0	2.6
DOE	$207	$0.5	1.3
NASA	$32	$0.0	0.0
NIH	$144	$3.0	7.8
NIOSH	$3	$3.1	8.1
DOC	$75	$0.9	2.3
USDA	$11	$0.5	1.3
EPA	$5	$4.0	10.4
DOJ	$2	$1.5	3.9
DHS	$1	$0.0	0.0
Total	**$1054**	**$38.5**	**100.0%**

Source: NNI FY 06 Supplement Report: p. 36, 38.

To coordinate environmental and safety research on nanotechnology, the National Science and Technology Council organized in October 2003 the interagency Nanotechnology Environmental and Health Implications Working Group (NEHI WG), composed of agencies that support nanotechnology research as well as those with responsibilities for regulating nanotechnology-based products. NEHI WG is in the process of developing a framework for environmental R&D for nanotechnology that it expects to release in January 2006. To provide useful guidance to agencies, Congress, academic researchers, industry, environmental groups, and the public, the research framework will need to define the scale and scope of the needed research, set priorities for research areas, provide information that can affect agency-directed spending decisions, and be specific enough to serve as overall research strategy for federal and non-federal research efforts.

Currently, over 60 percent of the environmental research funding is provided by the National Science Foundation (NSF). In FY05 and FY06, NSF is putting a small amount of funding (approximately $1 million each year) into a joint solicitation on investigating environmental and human health effects of manufactured nanomaterials with the Environmental Protection Agency,

[24] There is of course additional federal funding being spent on fundamental nanotechnology R&D that has the potential to inform future studies on environmental and safety impacts, so the $38.5 million may be a low estimate of the relevant research underway.

the National Institute for Occupational Safety and Health (NIOSH), and National Institute of Environmental Health Sciences (NIEHS). However, the majority of the NSF's funding in this area is distributed to projects proposed in response to general calls for nanotechnology-related research; projects are selected based on the quality and potential impact of the proposed research. It is not distributed based on the research needs of regulatory agencies such as EPA, OSHA or FDA. Currently NSF and the research community base their understanding of priorities in environmental research on a 2003 workshop "Nanotechnology Grand Challenge in the Environment,"[25] but the federal framework being developed by the NEHI WG should provide helpful, updated guidance for future research solicitations and proposals.

EPA's Office of Research and Development is the second largest sponsor of research on the environmental implications of nanotechnology, providing approximately 10 percent ($4 million) of the federal investment. At the beginning of the NNI, EPA focused its research program on the development of innovative applications of nanotechnology designed to improve the environment, but in FY03, EPA began to shift its focus to research on the environmental implications of nanotechnology. In FY04 and FY05, EPA has increasingly tailored its competitive solicitations to attract research proposals in areas that will inform decisions to be made by the agency's regulatory programs. In January 2006, EPA is planning to release an agency-wide nanotechnology framework that will describe both the potential regulatory issues facing the agency and the research needed to support decisions on those issues.

NIOSH sponsors 8 percent ($3 million) of research on environmental and safety implications of nanotechnology, and its activities are driven by the fact that minimal information is currently available on dominant exposure routes, potential exposure levels and material toxicity. NIOSH is attempting fill those gaps by building on its established research programs on ultra-fine particles (typically defined as particles smaller than 100 nanometers). The National Toxicology Program, an interagency collaboration between NIOSH and NIEHS, also supports a portfolio of projects studying the toxicity of several common nanomaterials, including quantum dots, buckyballs, and the titanium dioxide particles that have been used in cosmetics. NIOSH published a draft research strategy in late September 2005.

Private Sector Research

There is little information about how much individual companies are investing in research on the environmental and safety implications of nanotechnology. There are, however, a variety of activities underway in industry associations emphasizing the importance of research in this area. Members of the American Chemistry Council's ChemStar panel, for example, have committed to ensuring that the commercialization of nanomaterials proceeds in ways that protect workers, the public and the environment. Other elements of the chemical and semiconductor industries have formed the Consultive Boards for Advancing Nanotechnology, which has developed a list of key research and evaluation, identifying toxicity testing, measurement, and worker protection.

[25] "Nanotechnology Grand Challenge in the Environment: Research Planning Workshop Report," from the workshop held May 8-9, 2003, is available online at http://es.epa.gov/ncer/publications/nano/nanotechnology4-20-04.pdf.

Potential Regulatory and Policy Issues.

Some companies, especially large firms that operate in many industry sectors, have significant experience dealing with environmental issues and risk management plans, are comfortable dealing with potential environmental and safety implications arising from nanotechnology. However, many companies that are involved with nanotechnology-related products are small, start-up companies or small laboratories with less experience in this area. According to the Lux Research report described above, some of these small enterprises do not carry out testing because they lack the resources to do so, while others do not do so because of fear they might learn something that could create legal liability or create barriers to commercializing their product.

At EPA, the regulatory program offices are trying to determine whether and to what degree existing regulatory programs can and should be applied to nanotechnology. For example, EPA is considering how the Toxic Substances Control Act (TSCA) will apply to nanotechnology, having recently approved the first nanotechnology under that statute. (See Appendix A for a recent Washington Post article discussing the issue). Enacted in 1976, TSCA authorizes EPA to regulate new and existing chemicals and provides EPA with an array of tools to require companies to test chemicals and adopt other safeguards. Decisions on conventional chemicals under TSCA are driven by a chemical's name, test data, and models of toxicity and exposure. Because much of this information does not yet exist for nanotechnology, EPA is having a difficult time deciding how best to proceed. The lack of information led to EPA's recent proposal to create a voluntary program under which companies would submit information that would help the agency learn about nanotechnology more quickly. EPA is now evaluating all of its water, air and land regulatory responsibilities to determine whether and how EPA should handle nanotechnology in these areas.

Other federal agencies with regulatory responsibilities, such as the Food and Drug Administration and the Occupational Safety and Heath Administration, are also trying to determine how they will address environmental and safety concerns related to nanotechnology.

A number of observers, including the United Kingdom's Royal Society,[26] have suggested a precautionary approach to nanotechnology until more research has been completed. They urge caution especially regarding applications in which nanoparticles will be purposely released into environment. Examples of these so-called dispersive uses are nanomaterials used to clean contaminated groundwater or those that when discarded enter the sewer system and thereby the nation's waterways.

[26] The United Kingdom's Royal Society and Royal Academy of Engineering's report "Nanoscience and Nanotechnologies: Opportunities and Uncertainties" was published in July 2004 and is available online at http://www.nanotec.org.uk/finalReport.htm

9. Witness Questions

The witnesses were asked to address the following questions in their testimony:

Questions for Dr. Clayton Teague

In your testimony, please briefly describe current federal efforts to address possible environmental and safety risks associated with nanotechnology and address the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- How much is the federal government spending for research on environmental and safety implications of nanotechnology? Which agencies have the lead? What additional steps are needed?

Questions for Mr. Matthew Nordan

In your testimony, please briefly describe the major findings of the Lux Research report on environmental and safety issues associated with nanotechnology and address the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Dr. Krishna Doraiswamy

In your testimony, please briefly describe what DuPont is doing to address possible environmental and safety risks associated with nanotechnology and answer the following questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Mr. David Rejeski

In your testimony, please briefly describe the major findings of the Wilson Center's recent study on public perceptions about nanotechnology and answer the following four questions:

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Questions for Dr. Richard Denison

- What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?
- What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?
- What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?
- Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Appendix A: Washington Post Article on Nanotechnology and Safety

Nanotechnology's Big Question: Safety
Some Say Micromaterials Are Coming to Market Without Adequate Controls
The Washington Post
October 23, 2005, page A11
By Juliet Eilperin, Washington Post Staff Writer

With little fanfare, the Environmental Protection Agency has for the first time ruled on a manufacturer's application to make a product composed of nanomaterials, the new and invisibly small particles that could transform the nation's engineering, industrial and medical sectors.

The agency's decision to approve the company's plan comes amid an ongoing debate among government officials, industry representatives, academics and environmental advocates over how best to screen the potentially toxic materials. Just last week, a group of academics, industry scientists and federal researchers, working under the auspices of the nonprofit International Life Sciences Institute, outlined a set of principles for determining the human health effects of nanomaterial exposures.

By year-end, the EPA plans to release a proposal on how companies should report nanomaterial toxicity data to the government.

"Toxicity studies are meaningless unless you know what you're working with," said Andrew Maynard, who helped write the institute's report and serves as chief science adviser to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, a Washington-based think tank.

Because of their tiny size, nanomaterials have special properties that make them ideal for a range of commercial and medical uses, but researchers are still trying to determine how they might affect humans and animals. Gold, for example, may behave differently when introduced at nanoscale into the human body, where it is chemically inert in traditional applications.

The institute's report urged manufacturers and regulators to evaluate the properties of nanomaterials in laboratory tests, adding: "There is a strong likelihood that the biological activity of nanoparticles will depend on physiochemical parameters not routinely considered in toxicology studies."

The EPA decided last month to approve the "pre-manufacture" of carbon nanotubes, which are hollow tubes made of carbon atoms and potentially can be used in flat-screen televisions, clear coatings and fuel cells. The tubes, like other nanomaterials, are only a few ten-thousandths the diameter of a human hair.

Jim Willis, who directs the EPA's chemical control division in the Office of Pollution Prevention and Toxics, said he could not reveal the name of the company that received approval for the new technology or describe how that technology might be marketed. He added, however, that the

EPA reserved the right to review the product again if the company ultimately decides to bring it to market.

Nanomaterials are already on the market in cosmetics, clothing and other products, but these items do not fall under the EPA's regulatory domain. EPA officials judge applications subject to the Toxic Substances Control Act (TOSCA), a law dating from the mid-1970s that applies to chemicals.

In a Wilson Center symposium last Thursday, Willis said "it is a challenge" to judge nanotechnology under existing federal rules.

"Clearly, [TOSCA] was not designed explicitly for nanoscale materials," he said, but he added that chemicals "have quite a number of parallels for nanoscale materials" and that "in the short term, we are going to learn by doing."

Scientific studies also suggest nanoparticles can cause health problems and damage aquatic life. For instance, they lodge in the lungs and respiratory tract and cause inflammation, possibly at an even greater rate than asbestos and soot do.

"Nanoparticles are like the roach motel. The nanoparticles check in but they don't check out," said John Balbus, health program director for the advocacy group Environmental Defense. "Part of this is a societal balancing act. Are these things going to provide such incredible benefits that we're willing to take some of these risks?"

Nanomaterials have possible environmental advantages as well. For instance, they can absorb pollutants in water and break down some harmful chemicals much more quickly than other methods.

"Just because something's nano doesn't mean it's necessarily dangerous," said Kevin Ausman, executive director of Rice University's Center for Biological and Environmental Nanotechnology. He added that when it comes to nanotechnology's toxic effects, "we're trying to get that data before there's a known problem, and not after there's a known problem."

Companies such as DuPont are pushing to establish nanotechnology safety standards as well, in part because they have seen how uncertainties surrounding innovations—such as genetically modified foods—have sparked a backlash among some consumers.

"The time is right for this kind of collaboration," said Terry Medley, DuPont's global director of corporate regulatory affairs. "There's a general interest on everyone's part to come together to decide what's appropriate for this technology."